Ex 17 - MCKMDL00355349-5415

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

APPENDIX B

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

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distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1. Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.*, administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the